

SEP - 2 1999



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Teresa Stanek Rea
Burns, Doane, Swecker & Mathis, LLP
PO Box 1404
Alexandria, VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,867,907

NOTICE OF FINAL DETERMINATION and REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 4,867,907, which claims the food additive AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION® (2,2'-ethylidenebis(4,6-di-tertbutylphenyl)fluorophosphonite), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,268 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to this requirement for an election may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration and election, the Commissioner will issue a certificate of extension, under seal, for a period of 1,268 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 4, 1998 (63 Fed. Reg. 41580). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (935 - 253) + 1,995 \\ &= 2,336 \text{ days (6.4 years)}\end{aligned}$$

Since the regulatory review period began January 9, 1989, before the patent issued (September 19, 1989), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 9, 1989 to September 19, 1989 is 253 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 2,336 days,

would extend the patent from July 27, 2007 (35 U.S.C. § 154) to December 18, 2013 which is beyond the 14-year limit (the approval date is January 15, 1997, thus the 14 year limit is January 15, 2011). The period of extension is thus limited to January 15, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, July 27, 2007, to and including January 15, 2011, or 1,268 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Applicant has also filed an application for patent term extension of U.S. Patent No. Re. 36,128 (originally U.S. Patent No. 4,912,155) based upon the regulatory review of the food additive AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION®. No more than one patent may be extended based upon a regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby **REQUIRED TO ELECT** a single patent for extension. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified will be granted and the application for Reissue Patent No. 36,128 will be dismissed.

If applicant elects the above-identified patent, upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,867,907
Granted:	September 19, 1989
Original Expiration Date:	July 27, 2007
Applicant:	Lester P.J. Burton et al.
Owner of Record:	Albermarle Corporation
Title:	Aqueous Aryl Fluorophosphite Suspension
Classification:	252/400
Product Trade Name:	AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION® (2,2'-ethylidenebis(4,6-di- tertbutylphenyl)fluorophosphonite)

Term Extended: 1,268 days

Expiration Date of Extension: January 15, 2011

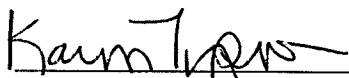
Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: AQUEOUS ARYL
FLUOROPHOSPHITE
SUSPENSION®
FDA Docket No.: 95E-0292